REMARKS

Applicant has carefully reviewed the Application in light of the Final Office Action dated February 19, 2010. Claims 1-20 are pending in this Application. Claims 1-3 and 18-20 stand rejected under 35 U.S.C. § 102. Claims 6-17 have been cancelled without prejudice or disclaimer. Claims 1 and 2 have been amended. Claims 22-24 have been added. Support for the amendments may be found, for example, in FIGURES 1, 2, and 4A and the supporting text of the Specification. Applicant respectfully requests reconsideration and favorable action in this case.

Rejections under 35 U.S.C. §102

Claims 1-3 and 18-20 stand rejected under 35 U.S.C. §102(e) as being unpatentable over U.S. Patent No. 5,910,252 to Truitt *et al.* (*Truitt*). Claim 1 is an independent claim that relates to a method for collecting a biological fluid. Independent Claim 1, as amended, includes the steps of:

> collecting a biological fluid by natural flow from a patient, without a pump;
>
> measuring a natural fluid flow rate of the biological fluid collected from the patient, the natural flow being based on venous pressure and gravity;
>
> ...
>
> the solution flow rate is adjusted while collecting the biological fluid from the patient based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation solution.

Support for the amendment may be found, for example, in Figures 1, 2, and 4A and the supporting text of the Specification. For example, referring to Page 9, Line 28 to Page 10, Line 1, the Specification discloses, "[b]iological fluid may collected by natural flow, that is to say gravity and the venous pressure of the donor." (emphasis added). There is no pump involved with the collection of the biological fluid. The only pump used is, for example, "a peristaltic pump with a single head which is able to move in rotation at variable speeds in order to pump the anticoagulant and/or preservation solution." (Specification, Page 9, Lines 26-28). Applicant submits *Truitt* fails to teach the recited elements, and therefore, cannot anticipate Claim 1.

Truitt Fails to Teach or Suggest a Natural Fluid Flow

First, Applicant submits that *Truitt* fails to teach or suggest a natural fluid flow. In the Final Office Action, the Examiner asserts that "Truitt make[s] it clear that blood is fed to the apparatus directly from an arterial or venous catheter, i.e., no pump is present." (Final Office Action, Page 2). Applicant disagrees. As presented in the Response filed on November 5, 2009, Applicant submits that *Truitt* clearly discloses using a pump coupled to the catheter, which the Examiner has failed to consider. Applicant submits that a prior art reference must be considered in its entirety, *i.e.,* as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); MPEP 2143.02.

Truitt discloses "a catheter 33 inserted into a vein or artery of the patient and flows into an access line 34 for supply to the apparatus 30." *Truitt* further discloses that coupled to catheter 33 is a first pump 52, where "the first pump 52 is operated when the blood to be treated is withdrawn from a vein of the patient 32 through a venous catheter 33." (Column 4, Lines 32-36; emphasis added). *Truitt* also discloses that

> the operator enters in the desired rate of blood flow through the primary circuit, ... [and] based upon the rate information collected ... each of the pumps 52, 62, 66 and 78 is individually and controllably operated by the control computer 102 to maintain the rates in accordance with the rate information.

(Column 12, Lines 37-59; emphasis added). *Truitt* then discloses that

> the pressure differential created by the first pump 52 forces blood from the venous source through the catheter 33 and into the primary circuit.

(Column 4, Lines 32-36; emphasis added). Thus, *Truitt* clearly discloses that in order to withdraw blood from patient 32 through catheter 33, the first pump 52 must be in operation. By suggesting the need to pump biological fluid, which the current claims collect by natural flow, *Truitt* actually teaches away from the claimed invention.

Truitt Fails to Teach or Suggest Measuring a Natural Fluid Flow Rate

As noted above, *Truitt* fails to teach or suggest a natural flow. Applicant further submits that *Truitt* fails to teach or suggest measuring a natural fluid flow rate of the biological fluid collected from the patient, as recited in Claim 1. The Examiner contends that *Truitt* discloses "measuring a fluid flow rate of the biological fluid comprises weighing the collected fluid via scales 92." (Final Office Action, Page 3). Applicant disagrees.

Truitt discloses measuring the entire content of a collection container with scale 92. For example, *Truitt* discloses a

> collection container 86 is provided to collect or receive matter from the blood transferred across the semi-permeable membrane 42 and/or to receive the used secondary fluid after it has passed through the secondary chamber 46... The fifth pump is connected to the collection line 82 for moving body fluid from the primary chamber 44 to the collection fluid container 86.

(Column 5, Line 61 through Column 6, Line 3; emphasis added). *Truitt* further discloses that

> [t]he collection container 86 is connected to scales 92 which weigh the content of the collection fluid which has been collected in the collection container...and the actual flow rate of the collection fluid is measured by scales 92.

(Column 5, Line 6 through Column 6, Line 11). Here, *Truitt* clearly discloses using pump 86 to transfer the fluids to collection container 86 and determining the flow rate from (1) blood transferred across membrane 42, (2) secondary fluid from a secondary chamber, and/or (3) body fluid moving from a primary chamber. Thus, the flow rate of the fluids collected by collection container 86 is not from a natural fluid flow rate from a patient, but rather fluids pumped from another chamber.

Truitt Fails to Teach or Suggest Adjusting a Solution Flow Rate

Claim 1 also recites "the solution flow rate is adjusted while collecting the biological fluid from the patient based upon the measured natural fluid flow rate." The Examiner contends *Truitt* discloses this element as

> computer 102 responds to signals from the scales, which weigh respective amounts of fluid and anticoagulant. Truitt then state in Col. 7, lines 1-4 that control signals from the computer 102 are delivered over the control signal path to control the operation of pumps 52, 62, 66, 78, and 84. This process of receiving monitor signals and executing control signals to control the operation of the pump is necessarily a disclosure of adjusting the fluid flow rate to preserve a selected ratio between the collected fluid and the anticoagulant.

(Final Office Action, Page 2). Applicant disagrees. *Truitt* merely discloses multiple, distinct, separate containers including a specific fluid, where each container is connected to a particular scale. For example, *Truitt* discloses container 68 is connected to scale 72 and contains replacement fluid, where scale 72 "weigh[s] the content of the replacement fluid within the replacement fluid container." (Column 5, Lines 31-34) *Truitt* discloses "secondary fluid container 76 is connected to scales 90 which weigh the secondary fluid in the secondary fluid container." (Column 5, Lines 59-60). *Truitt* further discloses a "collection container 86 is connected to scales 92 which weigh the content of the collection fluid which has been collected in the collection container." (Column 5, Lines 65-67). However, none of the containers 68, 76, and 86 includes a biological fluid collected from the patient.

Assuming, *arguendo,* the control signals that are received based on the weight can be used to adjust a flow rate as the Examiner contends, and Applicants does not concede, the adjustment is for the flow rate of the solution being held by the particular container and not for a solution rate, which again is the rate for pumping anticoagulant and/or preservation solution from a reservoir to the collected biological fluid, as recited in Claim 1. *Truitt* discloses

> [t]he signals from the scales 72a, 90a and 92a may be utilized by the control processor 122 to determine the weight of the particular fluid dispensed or collected. To determine the rate of fluid dispensing from or collecting into a particular container, the control processor 122 compares, at regular intervals (the higher the flow rate, the shorter the interval), the actual weight of the container to the desired weight. The desired weight can be calculated from the desired flow rate stored in the computer memory and the treatment time elapsed. If the actual weight and the desired weight differ, the control processor 122 controls the corresponding pump in order to decrease, and eventually to cancel, the difference. The control processor 122 takes into account the change in the difference since

> the latest comparison in order to avoid oscillations of the actual flow rate around the desired flow rate.

(Column 9, Lines 7-22). *Truitt* does not teach or suggest a solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation solution, as recited as Claim 1. Thus, the cited reference fails to anticipate Claim 1.

Given that Claims 2, 3 and 18-20 depend from Claim 1, Applicant respectfully submits that Claims 2, 3, and 18-20 are allowable. Applicant respectfully requests that the Examiner withdraw the rejections and allow Claims 1-3 and 18-20.

New Claims 21-24 are Allowable Over the Cited Reference

Claim 21 recites a method of collecting blood, including the steps of, "collecting blood by natural flow from a patient, without a pump," "measuring a natural fluid flow rate of the blood collected from the patient, the natural flow being based on venous pressure and gravity," "pumping anticoagulant and/or preservation solution from a reservoir to the collected blood at a solution flow rate", and "the solution flow rate is adjusted while collecting the blood based upon the measured fluid flow rate to preserve a selected ratio between the collected blood and the anticoagulant and/or preservation solution."

As noted above with respect to the rejections under 35 U.S.C. §102, Truitt teaches away from collecting a biological fluid by natural flow.

Truitt also fails to teach or suggest other elements of new Claim 21, such as "measuring a natural fluid flow rate of the blood collected from the patient, the natural flow being based on venous pressure and gravity," and "the solution flow rate is adjusted while collecting the blood based upon the measured fluid flow rate to preserve a selected ratio between the collected blood and the anticoagulant and/or preservation solution." (emphasis added). *Truitt* discloses how much fluid is collected in a collection container, *e.g.*, determines the weight of the fluid in the collection container. (Column 5, Lines 61-67). *Truitt* also discloses adjusting the flow rate of a

particular fluid of the collection container to achieve a desired weight. (Column 9, Lines 7-22). The cited reference, therefore, fails to disclose the recited limitations and cannot anticipate Claim 21.

Given that new Claims 22-24 depend from Claim 21, Applicant respectfully submits that Claims 22-24 are allowable. As such, Applicant respectfully requests that the Examiner allow Claims 21-24.

No Waiver

All of Applicant's arguments and amendments are without prejudice or disclaimer. Additionally, Applicant has merely discussed example distinctions from the references relied upon. Other distinctions may exist, and Applicant reserves the right to discuss these additional distinctions in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Examiner, Applicant does not acquiesce to the Examiner's additional statements. The example distinctions discussed by Applicant is sufficient to overcome the rejections asserted in the present Office Action.

Request for Continued Examination (RCE)

Applicant encloses a Request for Continued Examination (RCE) Transmittal, and the Commissioner is hereby authorized to charge the RCE filing fee of $810.00 to Deposit Account No. 50-2148 of Baker Botts L.L.P.

CONCLUSION

Applicant appreciates the Examiner's careful review of the application. Applicant has made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. For the foregoing reasons, Applicant respectfully requests reconsideration of the rejections and full allowance of the pending claims as amended.

Applicant encloses a Three-Month Petition for Extension of Time, and the Commissioner is hereby authorized to charge the $1,110.00 extension fee to Deposit Account No. 50-2148 of Baker Botts L.L.P. Applicant believes there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.322.2580.

Respectfully submitted,
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Date: August 17, 2010

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Enclosures:

1. RCE Transmittal
2. Petition for Extension of Time